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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,898	03/07/2005	Eiji Tsuru	Q86527	7841
23373 7590 03/26/2007 SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037			EXAMINER KOSACK, JOSEPH R	
			ART UNIT	PAPER NUMBER
			1626	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		03/26/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/526,898

Applicant(s)

TSURU ET AL.

Examiner

Joseph Kosack

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>01/29/2007</u> .  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Claims 1-18 are pending in the instant application.

#### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submissions filed on December 27, 2006 and January 29, 2007 have been entered.

#### ***Information Disclosure Statement***

The Information Disclosure Statement filed January 29, 2007 has been considered by the Examiner. The documents JP-7-330726A and JP 2000-247998 are not currently considered as they have previously been submitted on the IDS of March 7, 2005 and subsequently considered.

#### ***Previous Claim Rejections - 35 USC § 103 and Obviousness Double Patenting***

Claim 1 was rejected in the action mailed on February 6, 2006 under 35 U.S.C. 103(a) as being unpatentable over Yamagishi et al. (JP07-330726A) in view of Williamson (*Macroscale and Microscale Organic Experiments* 1999, pages 39 and 48-50).

Claims 2-17 were rejected in the action mailed on February 6, 2006 under 35 U.S.C. 103(a) as being unpatentable over Yamagishi et al. (JP07-330726A) in view of

Williamson (*Macroscale and Microscale Organic Experiments 1999*, pages 39 and 48-50) and Kitazawa et al. (USPN 5,387,603).

Claims 2-17 were rejected in the action mailed on February 6, 2006 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 12-13 of U.S. Patent No. 5,387,603 in view of Yamagishi et al. (JP07-330726A) and Williamson (*Macroscale and Microscale Organic Experiments 1999*, pages 39 and 48-50).

Applicant has submitted a declaration from Eiji Tsuru under 37 C.F.R. 1.132 to provide evidence to overcome the obviousness rejections.

The declaration under 37 CFR 1.132 filed December 27, 2006 is sufficient to overcome the rejections based upon the evidence that the alpha form of the crystal could not be obtained via the Examiner's stated process. The rejections are withdrawn.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-18 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In In re Wands, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

*The Nature of the Invention*

The nature of the invention is the alpha form of the compound currently known as KMD-3213 is claimed, along with medicaments and a method of using the crystal.

*The State of the Prior Art and the Predictability or Lack Thereof in the Art*

The prior art teaches the compound and similar methods of crystallization. For example, Yamagishi et al. (JP07-330726A) teach the dissolving of crude crystals in heated ethyl acetate, and allowing the solution to stand at room temperature. See Reference Example 30, page 24, paragraph 184.

The lack of predictability of the art has been established by the two declarations under 37 CFR 1.132 executed by Eiji Tsuru on June 13, 2006 and December 27, 2006 to show that that process, even with minor modifications known in the art, would produce the beta form of the crystal and not the alpha form. The basis for showing that the prior art process does not produce the alpha form is that a different process of making the compound was used in the instant application, which was **not** disclosed

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originally and was disclosed in the declaration. There is no evidence as to when, if ever, the process was publicly disclosed before, therefore it must be currently assumed that this is the first disclosure of the instant process.

*The Amount of Direction or Guidance Present and the Presence or Absence of Working*

*Examples*

The written description states that the alpha form can be made by dissolving crude crystals in heated ethyl acetate and allowed to stand at room temperature. The description does not state how the crude crystals were obtained. The Examiner originally interpreted this to mean that any crude crystal can be used to perform this process and made rejections under 35 U.S.C. 103(a) in the actions of February 6, 2006, and July 27, 2006.

*The Breadth of the Claims*

The breadth of the claims is the alpha form of the compound currently known as KMD-3213 is claimed, along with medicaments and a method of using the crystal.

*The Quantity of Experimentation Needed*

The quantity of experimentation needed is undue experimentation. One of skill in the would have had to come up with the process for making the compound that was kept secret, in order to generate the proper crude crystals referred to in the Examples in the specification.

*The Level of Skill in the Art*

The level of skill in the art of organic synthesis and pharmaceuticals is high. However, due to the unpredictability in the art as described above, one of ordinary skill

would be unable to make or use the claimed compound without undue experimentation in order to practice the invention as claimed.

Thus, the specification fails to provide sufficient support of the preparation and use of the alpha form of the compound currently known as KMD-3213. As a result, the application would require one of skill to perform an exhaustive search and an inordinate number of experiments in order to make or use the claimed polymorph.

Therefore, in view of the Wands factors and *In re Fisher* (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to test which diseases can be treated by the compound encompassed in the instant claims, with no assurance of success.

### ***Conclusion***

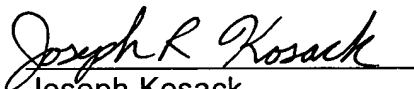
Claims 1-18 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Kosack whose telephone number is (571)-272-5575. The examiner can normally be reached on M-F 5:30 A.M. until 2:00 P.M.

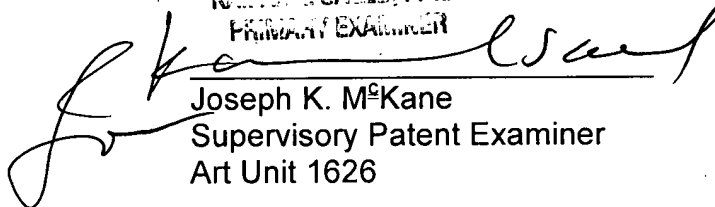
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571)-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Joseph Kosack  
Patent Examiner  
Art Unit 1626



KANE, J. K., P.D.  
PRIMARY EXAMINER

Joseph K. McKane  
Supervisory Patent Examiner  
Art Unit 1626